

Response Under 37 C.F.R. 1.116

Applicant: Kenneth M. Adams et al.

Serial No.: 10/657,915

Filed: September 9, 2003

Docket No.: M190.145.101 / P0000263.00 US

Title: SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY**REMARKS**

This is responsive to the Final Office Action mailed January 24, 2008. In that Office Action, the Oath/Declaration as filed was deemed defective. Claims 1-13, 17, 22, 23, 31, 32, and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams, U.S. Patent No. 6,503,263 ("the Adams '263 Patent") in view of Marino et al., U.S. Patent No. 6,280,447 ("Marino"). Claims 15, 16, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of Toriumi et al., U.S. Patent No. 6,214,009 ("Toriumi"). Claims 18, 19, and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of Adams, U.S. Patent No. 6,312,438 ("Adams '438 Patent"). Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino in view of Adams '438 Patent. Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino and further in view of West, Jr., U.S. Patent No. 5,364,395 ("West").

With this Response, the claims have not been amended. Claims 1-13, 15-24, and 31-36 remain pending in the application and are presented for reconsideration and allowance.

Rejection of Declaration / Oath

The Final Office Action asserts that the Oath or Declaration as filed was defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to the patentability as defined in 37 C.F.R. 1.56.

In response, Applicant respectfully references the Notice issued by Under Secretary Dudas on January 28, 2008 (published February 12, 2008 at 1327 O.G. 113) in which the Office waived the express language requirement of 37 C.F.R. 1.63(b)(3) for certain Oaths or Declarations filed prior to June 1, 2008. In particular, an Oath or Declaration filed prior to June 1, 2008 and containing the language "material to examination" or "in accordance with §1.56(a)" or both, will be accepted as acknowledging the Applicant's duty to disclose information "material to

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patentability” as defined in 37 C.F.R. 1.56. The Declaration associated with the pending application was filed prior to June 1, 2008, and recites one or both of the phrases specified in the Notice. Therefore, it is respectfully submitted that the Oath or Declaration as filed is acceptable, and that a new Oath or Declaration is not required.

35 U.S.C. §103 Rejections

In rejecting claim 1 as being unpatentable over the Adams ‘263 Patent in view of Marino, the Office Action acknowledges that the Adams’ 263 Patent “fails to disclose the specific shape/configuration of the pocket region” as claimed. To address this deficiency, the Office Action summarily concludes that the claimed shape/configuration of the pocket “is one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a pocket region”. In support of this assertion, the Office Action cites *In re Dailey and Eilers*, 149 USPQ 47 (1966). Applicant respectfully disagrees.

As a starting point, it is respectfully submitted that the Office Action’s reliance upon *In re Dailey* is misplaced. *In re Dailey* related to a patent for disposable nursing containers for infants, with the patent-at-issue reciting claim limitations directed toward a plastic nursing container with a bottom section having a shape that readily collapses upon withdrawal of container contents, in combination with a nipple having a particular slit configuration. The combination nipple and container was discussed at length in the *In re Dailey* Opinion. In addition, the Opinion made passing reference to a dependent claim reciting that the bottom section of the container was “a portion of a sphere less than a hemisphere.” It is to this relatively generic claim language (i.e., “a portion of a sphere less than a hemisphere”) that the passage of *In re Dailey* now relied upon by the Office Action is relevant. That is to say, the holdings of *In re Dailey* relating to “mere matter of choice” appears applicable only to a claim limitation of “less than a hemisphere.” In contrast, the pending claims relate to surgical micro-burring instruments, and recite various details directed toward a structural configuration of the pocket. For example, claim 1 provides that the pocket:

- includes a side wall having a proximal zone, an intermediate zone, and a distal zone;

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- the proximal zone extends downwardly from the proximal portion [of the outer tube] toward the bottom surface;
- the intermediate zone extends from the proximal zone at an angle of extension relative to the proximal zone that differs from an angle of extension of the proximal zone relative to the proximal portion; and
- the distal zone extends downwardly from the intermediate zone toward the bottom surface at an angle of extension differing from the angle of extension of the intermediate zone relative to the proximal zone.

Clearly, the subject matter and above-highlighted claim features are distinct from the facts of *In re Dailey*. The relatively generic phrase of “less than a hemisphere” is simply not comparable to one or more (or all) of the limitations of claim 1 identified above. Under these circumstances, the Examiner may not rely upon *In re Dailey* in formulating an obviousness rejection. *MPEP §2144*. In fact, *In re Dailey* has not been cited in any subsequent, published Board of Patent Appeals or Court of Appeals for the Federal Circuit decision.

In light of the above, it is respectfully submitted that claim 1, as well as all claims depending therefrom, are not made obvious by the Adams ‘263 Patent in view of Marino. The Adams ‘263 Patent clearly does not teach several limitations; the Final Office Action directly concedes this deficiency. To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). Pointedly, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007). In order to sustain a rejection based on “design choice,” the Examiner must provide reasoning why a specific feature is a matter of design choice and therefore obvious. *In re Chu*, 36 USPQ2d 1089 (Fed. Cir. 1995). The Office Action fails to provide any explanation, explicit or otherwise, as to how the specific limitations of claim 1 relating to the pocket would have been obvious to one of skill.

In fact, by characterizing the pocket structural configuration of claim 1 as being “one of numerous shapes or configuration,” it appears that the Examiner is improperly applying an

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“obvious to try” rationale in support of the obviousness rejection. According to the Final Office Action’s theory, what would have been “obvious to try” would have been to vary all parameters of the pocket-forming structure to try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gives no indication of which parameters are critical and no direction as to which of many possible choices is likely to be successful. Under these circumstances, a *prima facie* case of obviousness cannot be maintained. *MPEP §2145.X*.

For at least the above reasons, withdrawal of the rejections is respectfully requested. For purposes of appeal, Applicant hereby maintains all previously-presented arguments relating to allowability of the claims.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-13, 15-24, and 31-36 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-13, 15-24, and 31-36 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant’s representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

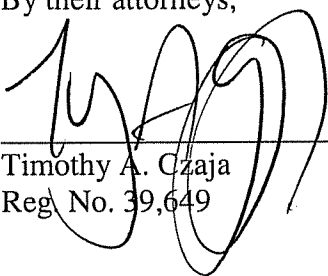
Kenneth M. Adams et al.,

By their attorneys,

Date:

March 21, 2008

TAC:jms



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